

SUMMARY: Safety and Effectiveness Information for VIDAS CKMB Assay

The VIDAS CKMB assay determines the concentration of creatine kinase MB isoenzyme in serum or plasma (heparin or EDTA). It is substantially equivalent to the Ciba-Corning Magic Lite CK-MB assay.

Safety and effectiveness issues relevant to ELFA methodology for quantitative immunochemistry assays such as those for creatine kinase MB may include poor correlations, poor sensitivity, cross-reactivity, interference, or imprecision.

1. Correlations:
 - a. Comparison of the VIDAS CKMB assay with the Ciba-Corning Magic Lite CK-MB assay yields a line with the equation $y = 0.83x + -0.656$ and a correlation coefficient of 0.97.
 - b. The calibrator in the kit ensures that the master curve stored by the VIDAS instrument is valid for the shelf life of that kit. The body of data supports the use of a single calibrator run in duplicate for this purpose.
2. Sensitivity: The VIDAS CKMB assay is designed to measure creatine kinase MB levels between 0.8 ng/ml and 300 ng/ml. The lowest measurable level of creatine kinase MB (assay sensitivity) that can be distinguished from zero with 95 % probability using the VIDAS assay is 0.8 ng/ml.
3. Cross-reactivity: Specificity studies demonstrate that the antibodies used in the VIDAS CKMB assay is specific for Creatine Kinase MB isoform. No cross-reactivity is seen with isoforms BB and MM.
4. Interfering Substances
 - a. No interference in VIDAS CKMB assay performance was seen with serum collected in dry glass tubes with glycerolated cap, tubes containing a separating gel, siliconized tubes, and non-siliconized tubes, tubes containing EDTA and tubes containing heparin.
 - b. No interference in the VIDAS CKMB assay performance was seen with the range of concentrations of hemoglobin, lipids, or bilirubin tested.
5. Precision/Reproducibility
 - a. Intra-assay precision studies showed coefficients of variation ranging from 3.2 % to 6.2 % over the reportable range of the assay.
 - b. Inter-assay reproducibility over an eight-week time period yields coefficients of variation that do not exceed 7.2 %.
 - c. Inter-assay, inter-instrument reproducibility for five different serum samples in nine assays on different instruments yields coefficients of variation that do not exceed 16.7 %.

When the VIDAS CKMB assay is used as instructed in the package insert, the above statements are true. The package insert should always be consulted along with the Operator's Manual to ensure that the assay is being performed properly. For additional information, references are listed in the package insert.